

NH Laws / Rules Regarding Limited Retail Drug Distributors

318:1, VII-a. "Limited retail drug distributor" means a distributor of legend devices or medical gases delivered directly to the consumer pursuant to a practitioner's prescription order, or federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored, or dispensed to patients pursuant to the order of an authorized practitioner.

318:51-b Licensing of Limited Retail Drug Distributors Required. –

I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board. Such license shall expire annually on June 30. An application together with a reasonable fee as established by the board shall be filed annually on or before July 1.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the board that:

(a) The applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) The applicant has sufficient space and security equipment as to properly carry on the business described in the application.

(c) The license granted by this chapter shall at all times be displayed in a conspicuous place in the facility for which it is issued.

(d) The applicant, other than a distributor of legend devices or medical gases, has a written contract with a pharmacist licensed in the state to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section is subject to the provisions of RSA 318:29.

CHAPTER Ph 600 LIMITED RETAIL DRUG DISTRIBUTOR

Statutory Authority: RSA 318:51-b

PART Ph 601 LICENSING OF LIMITED RETAIL DRUG DISTRIBUTORS

Ph 601.01 License required

(a) No person shall act as a limited retail drug distributor, as defined in RSA 318:1,VII-a, without first obtaining a license to do so from the board according to RSA 318:51-b.

(b) No license shall be issued or renewed for a limited retail drug distributor unless the same shall be operated in a manner prescribed by RSA 318:51-b and according to Ph 600.

(c) Separate licenses shall be required for each site owned and operated by the limited retail drug distributor.

(d) The board shall provide, on an annual basis, a license renewal to all licensed limited retail drug distributors.

(e) The prescribed fee for annual and renewal licenses for limited retail drug distributors shall be:

- (1) For clinics under contract with the department of health and human services (DHHS), \$150; and
- (2) For methadone maintenance/detoxification treatment centers, \$250.

Ph 601.02 Obtaining and Filing a License Application.

Applications for licensure of limited retail drug distributors may be obtained from and filed at the board office, identified in Ph 103.03.

Ph 601.03 Application Contents.

(a) The applicant for licensure shall supply, on form MM-1, at least the following:

- (1) Name of the facility;
- (2) Address of the actual location where business is conducted;
- (3) Identification of ownership;
- (4) Hours of operation;
- (5) List of persons with access to the drug supply;
- (6) Signature of the person responsible for the licensed location and date signed;
- (7) Identity of the consultant pharmacist; and
- (8) Identity of the medical director.

(b) The applicant shall also submit a scaled drawing of the facility.

(c) The applicant shall supplement the application specified in (a) and (b) above with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements of part Ph 600.

(d) If the applicant is a corporation, or the limited retail drug distributor will be operated under a corporate name, a certificate from the NH secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the state of New Hampshire under the corporate name.

(e) If the applicant proposes to hold, store or dispense controlled substances as a methadone maintenance/detoxification facility, the application shall be supplemented with the following information:

- (1) A brief description of the security system; and
- (2) A list of all persons with access to the controlled substances.

(f) The applicant shall supplement the application specified in (a) above with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements for operation of a drug abuse treatment facility.

(g) If the application is for a methadone maintenance/detoxification facility, the applicant shall submit the current registration number issued by the federal drug enforcement administration (DEA).

Ph 601.04 Consultant Pharmacist. All applicants licensed under the provisions of RSA 318:51-b shall have a written contract with a pharmacist, licensed in NH, to serve as a consultant on all matters relating to procurement, storage and dispensing of prescription drugs as defined in RSA 318:1, XVII.

Ph 601.05 Changes in Supporting Information. The applicant shall notify the board, immediately, of any changes of information from that which was submitted on the original application pursuant to Ph 601.03. Failure to report changes shall result in the imposition of a \$25 administrative fee. No license shall be issued until all fees are paid in full.

Ph 601.06 Renewal Applications.

(a) The license period shall be from July 1 thru June 30 of the following year.

(b) Applications for renewal of a license to operate as a limited retail drug distributor shall consist of the application as described in Ph 601.03 and the prescribed fee as indicated in Ph 601.01(e).

Ph 601.07 Temperature. The temperature in any area wherein drugs are stored, manufactured, compounded or dispensed, shall, at all times, be in compliance with the standards established by the United States Pharmacopoeia as defined in Ph 701.02(r).

Ph 601.08 Quarantine. Any drug, which is adulterated as defined in Ph 701.02(a) or misbranded as defined in Ph 701.02(i), shall be removed from the routine stock and held in a specifically designated secure area of the facility pending proper and safe disposition.

Ph 601.09 Space. Drugs shall be housed in a well-lighted and ventilated room or department with clean and sanitary surroundings.

Ph 601.10 Security.

(a) That portion of the facility where drugs are stored, compounded or dispensed, shall be lockable so as to prevent entry into that area by any person or persons without the knowledge of the authorized individuals on duty, or when the facility is not open.

(b) If the facility contains controlled substances, it shall be equipped with a suitable alarm system as referenced in Ph 309.06.

(c) Methadone maintenance/detoxification facilities shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting to illuminate the outside perimeter of the premises.

(d) All controlled substances shall be stored pursuant to the security provisions outlined in 21 CFR 1301.72(a).

(e) For those facilities which are open to the public 24 or more hours per week, the consultant pharmacist shall visit, at least monthly, all areas of the facility where drugs are stored to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any drugs not conforming to these standards shall be removed from stock. For facilities which are open to the public less than 24 hours per week, such visits shall be conducted on a quarterly basis.

(f) The consultant pharmacist shall create a written record of each monthly and/or quarterly inspection, specified in (e), which shall be maintained on site and available to the board upon request.

(g) The pharmacist shall ensure that the areas specified in (e) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(h) The consultant pharmacist shall develop a distribution system, which shall prevent the illegal diversion of drugs. Where applicable, the inventory of all schedule II controlled substances and other controlled drugs as required by federal law stored in any area of the facility, shall be checked by 2 persons at least every 24 hours and accountability records shall be completed by the nursing or medical staff and maintained on-site for inspection by the consultant pharmacist, except:

(1) In situations at the methadone maintenance/detoxification facilities that result in only one staff member being present, the inventory shall be counted, signed, dated and shall be “cosigned” immediately upon the presence of a second staff member.

(2) At no time shall there lapse more than 72 hours before this inventory verification by a second party.

Ph 601.11 Dispensing Practices.

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, physician, advanced registered nurse practitioner, physician assistant, or registered nurse, as identified in RSA 318:42, VII (a), in compliance with state and federal pharmacy-related laws and rules.

(b) In the case of methadone maintenance/detoxification facilities and according to the provisions of RSA 318:42, VII(a), the dispensing of narcotics is extended to employees of the clinic, authorized in writing according to the provisions of 21 CFR 1301.74(i) of the federal law.

(c) No finished prescription shall be left outside of the drug storage area of the facility for pick-up when the licensed practitioner is not present at the facility.

(d) In the case of methadone maintenance/detoxification facilities, all drugs shall remain in the designated and secured medication room at all times.

Ph 601.12 Deliveries.

(a) All drug order deliveries containing prescription drugs shall be delivered only when a licensed practitioner is on the premises in order to secure such drug orders.

(b) In the case of methadone maintenance/detoxification facilities, drug deliveries may be accepted only by the licensed practitioner or other individuals identified according to the requirements of 21 CFR 1301.74(h).

Ph 601.13 Access to Drug Supply.

(a) Only the pharmacist, physician, advanced registered nurse practitioner, physician assistant or registered nurse, as identified in RSA 318:42, VII (a), shall have access to the drug supply.

(b) In the case of methadone maintenance/detoxification facilities, access to the drug storage area may also be extended to licensed practical nurses provided such authorization is granted, in writing, according to the provisions of 21 CFR 1301.72(d) of the federal law.

(c) Methadone maintenance/detoxification facilities shall supply the board with a list of all individuals that have been granted access to the drug supply, and, should this list change, the board shall be notified, in writing, within 72 hours of such changes.

Ph 601.14 Dispensing Records.

(a) A readily retrievable record, completed by the nursing or medical staff, shall be made of all administration or dispensing of prescription drugs from the facility.

(b) The record, as specified in (a) above, shall be separate from the patient's medical record and include:

- (1) Name and address of the patient;
- (2) Date of administration or dispensing;
- (3) Name, strength and quantity of drug(s) administered or dispensed;
- (4) Identity of the prescriber; and
- (5) Signature of the person administering or dispensing.

(c) Methadone maintenance/detoxification facilities shall maintain a dispensing log, completed by the nursing or medical staff, containing the following information:

- (1) Name of substance;
- (2) Strength of substance;
- (3) Dosage form;
- (4) Date administered;
- (5) Patient identification number;
- (6) Amount consumed;
- (7) Amount and dosage form taken home; and
- (8) Dispenser's signature.

(d) Records of administration and dispensing as specified in (b) and (c) above shall be maintained for a period of 4 years. Such records shall be open to inspection by the pharmacy board and its agents.

Ph 601.15 Prescription Labels.

(a) Whenever an authorized practitioner dispenses a controlled drug, as defined in RSA 318-B:1-a and b, or a non-controlled prescription drug, as defined in RSA 318:1, XVII, he/she shall affix to the container in which such drug is dispensed, a label showing at least:

- (1) Name and address of the facility;
- (2) Name of the patient;
- (3) Date dispensed;
- (4) Name, strength and quantity of drug dispensed;
- (5) Directions for use;
- (6) Name of the prescribing practitioner;
- (7) Name or initials of the dispensing practitioner; and
- (8) All pertinent auxiliary labels.

Ph 601.16 Labeling Exemption. The labeling requirements, as specified in Ph 601.15, shall be exempted when medication is being administered, for immediate consumption, such as in a methadone maintenance/detoxification facility.

Ph 601.17 Violations. Any person who distributes legend drugs according to RSA 318:51(b) and the provisions of Ph 600, shall be subject to disciplinary action as provided in RSA 318:29.